

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/733,488 Confirmation No. 7675
Applicants : Yaron ILAN, et al.
Filed : December 10, 2003
Title : REGULATION OF IMMUNE RESPONSES BY MANIPULATION
OF INTERMEDIARY METABOLITE LEVELS
TC/Art Unit : 1648
Examiner: : Emily M. Le
Docket No. : 59046.000044 (Formerly Enz-64(D3))
Customer No. : 21967

RESPONSE TO RESTRICTION REQUIREMENT OF MAY 19, 2004

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

In the Office Action of May 19, 2004, the Examiner requested restriction under 35 U.S.C. § 121 to one of Groups I-V, which are purportedly distinct inventions. Applicants hereby provisionally elect Group V, which covers claims 50-62, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, according to the Office Action, with **traverse**. Applicants hereby provisionally elect the species of infection, with **traverse**. Applicants hereby provisionally elect the species of viral, with **traverse**. Applicants hereby provisionally elect the species of HCV, with **traverse**. Applicants reserve the right to file divisional application(s) directed to non-elected subject matter.

(435/262) and Groups III and IV sharing the same class and subclass (435/267). Therefore it is evident from overlapping method steps, overlapping class and subclass, and overlapping preambles, that a search of the subject matter of Groups I, II, III, IV, and V does not constitute a serious search burden for the Examiner.

Secondly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between the three diseases (cancer, infection, and immune dysfunction) as distinct and independent. It is also unclear from the Office Action whether this second requirement was a restriction between inventions or a species election. Applicants note that the subject matter of the Groups focuses on administering a metabolite and as such search of the use of a metabolite will encompass several diseases including but not limited to cancer, infection, and immune dysfunction. For instance, the specification teaches that the immune system monitors both infection and metabolic processes (pp. 8). Thus the immune system, and hence infection by both bacteria and viruses, is linked to immune dysfunction. Also, the immune system is intimately involved in the regulation of tumor cells. Further the specification teaches that HCV causes both immunosuppressive and immunoreactive responses in an infected subject demonstrating the relationship between immune dysfunction and infection (pp. 9).

Thirdly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between two infectious agents (bacteria and viruses) as distinct and independent. It is also unclear from the Office Action whether this third requirement was a restriction between inventions or a species election. Additionally, it is improper to restrict between bacterial and viral infection as the preamble of the method claims centers on treatment of a disease using a metabolite or a reagent which increases metabolite levels. Also search of the use of a metabolite or reagent which increased metabolite levels would encompass both bacterial and viral infections.

Further, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between three viruses: HBV, HCV, and HIV. All three viruses infect the same host (humans) via a similar transmission method and often co-infect an individual. Thus the three viruses share a common structure and function in accordance to *In re Harnish* 631

F.2d 716, 206 USPQ 300 (CCPA 1980) and it is inappropriate to restrict between the three viruses.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all claims be allowed to be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants reaffirm the election with **traverse** of claims 50-62 (Group V), holding claims 1-49 in abeyance under the provisions of 37 C.F.R. § 1.142(b) until final disposition of the elected claims.

CONCLUSION

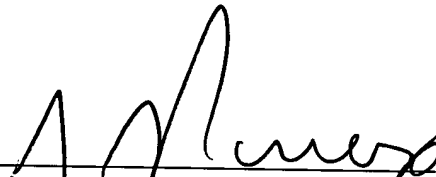
Applicants maintain that the restriction requirement is improper and that all pending claims, *i.e.*, claims 1-62, should be examined for patentability. If the Examiner believes that the prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

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Dated: August 2, 2005

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